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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,826	01/31/2006	Akio Kimura	06067/HG	8012

1933 7590 06/02/2010

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EXAMINER	
VU, JAKE MINH	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
06/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,826	KIMURA ET AL.	
	Examiner	Art Unit	
	JAKE M. VU	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-13* is/are pending in the application.

4a) Of the above claim(s) *8 and 9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/31/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Election Requirement Response filed on 03/03/20110; Information Disclosure Statement filed on 07/31/2009; and Amendment filed on 10/30/2009.

- Claims 1-7 have been cancelled.
- Claims 10-13 have been added.
- Claims 8-13 are pending in the instant application.
- Claims 8-9 have been previously withdrawn from consideration.

Election/Restrictions

Applicant's election with traverse of in the reply filed on 03/03/2010 is acknowledged. Applicant argument is found persuasive. The election requirement **is withdrawn**.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The prostaglandin F2α with a fluorine atom derivatives does not meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus of derivatives of prostaglandin F2α with a fluorine atom encompassed by the claim, since there is no description of the structural relationship of these derivatives provided in the specification and Applicant has not provided a description as to how the base molecule may be changed while remaining a derivative.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over MORISHIMA et al (WO 02/22131 published on 03/21/2002; wherein US 2004/0097592 is used as a translation) in view of KOIDE et al (JP 07-033650; translation provided) **are withdrawn** in view of Applicant's cancellation of these claims.

However, upon further consideration of Applicant's Amendment, a new ground(s) of rejection is made as discussed below.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over MORISHIMA et al (WO 02/22131 published on 03/21/2002; wherein US 2004/0097592 is used as a translation) in view of KOIDE et al (JP 07-033650; translation provided).

Applicant's claims are directed to a product comprising of: prostaglandin F2α derivative having a fluorine atom, such as 16-phenoxy-15-deoxy-15,15-difluoro-17,18,19,20-tetranorprostaglandin F2α; a resin container formed from a polymer alloy of polyethylene terephthalate and polyarylate. Additional limitations include: liquid preparation; ratio of 1:2 to 2:1; inhibiting the decrease of the prostaglandin F2α derivative.

MORISHIMA teaches a product comprised of: prostaglandin F2α derivative having a fluorine atom, such as 16-phenoxy-15-deoxy-15,15-difluoro-17,18,19,20-tetranorprostaglandin F2α (see US 2004/0097592 at [0024]); nonionic surfactant, such as polysorbate 80 (see [0004]); a resin container, such as a polymer of polyethylene terephthalate or acrylic resin (see [0014]). Additional disclosures include: ophthalmic

solution (see [0001]), which reads on liquid preparation; inhibiting the active ingredient to be adsorbed to a resinous container (see abstract).

MORISHIMA does not specifically teach a resin container containing a copolymer of polyethylene terephthalate AND polyarylate with a ratio of 1:2 to 2:1.

KOIDE teaches using a resin container containing polyethylene terephthalate AND polyarylate (see translation at [0009]) for eye drop solutions containing nonionic surfactant (see [0006]). Additional disclosures include: the resin inhibits photolysis of the active ingredient (see [0001]) and inhibits the transference and adhesion of the active ingredient to the container (see [0002]); thus inhibiting the decrease of the active ingredient (see [0003]), which is the same objective as Applicant's claimed invention.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate MORISHIMA's ophthalmic product into KOIDE's resin container containing a polymer alloy of polyethylene terephthalate AND polyarylate. The person of ordinary skill in the art would have been motivated to make those modifications, because it is known that the resin container inhibits photolysis of ophthalmic drug and inhibits the transference and adhesion of the drug to the container; thus inhibiting the decrease of the active drug. The person of ordinary skill in the art reasonably would have expected success because both reference dealt with inhibiting the decrease of active agents in eye drop formulation using non-ionic surfactant and resin containers.

The references do not specifically teach adding the ingredients in the ratio amount as claimed by Applicant. The amount of a specific ingredient in a polymer is

clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of ratio in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Response to Arguments

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the primary reference teaches Applicant's prostaglandin F2α derivative and the secondary reference teaches the Applicant's resin container formed from a polymer alloy of polyethylene terephthalate and polyarylate, wherein the resin container protects the ophthalmic drug. It would have been obvious to one skilled in the art to place the prostaglandin derivative into the resin container, since it is known that the resin container inhibits photolysis of the ophthalmic drug and inhibits the transference and adhesion of the drug to the container; thus inhibiting the decrease of the active drug, which is the same objective as Applicant's claimed invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE M. VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618